REMARKS

By this Amendment, claims 1-13 have been canceled, and new claims 14-25 have been added. Accordingly, claims 14-25 are pending in the application. Claims 14 and 20 are the independent claims. In view of the above amendments and the following remarks, favorable reconsideration of this application is respectfully requested.

The Examiner requested English-language translations of the art cited in the Information Disclosure Statement filed October 15, 2001, if available. Applicants have provided with this Amendment a copy of the WPindex-abstract of DE 42 40 681 in English; there are no English counterparts of WO 98/50091 and WO 00/09182. As for EP 0 358 873, the subject matter thereof corresponds with U.S. Patent No. 5,230,341.

The Examiner objected to the drawings as containing informalities. By this Amendment, Applicants have amended the specification to correct informalities noted therein, and have also provided herewith a Letter to the Official Draftsperson on a separate sheet. Support for the new figure is found in the specification at page 8, lines 11-12.

The Examiner rejected claims 1-13 under 35 U.S.C. 112, first and second paragraphs, and further rejected claim 1 under

35 U.S.C. 101. Applicants have cancelled claims 1-13 and submitted new claims 14-25 which are in conformity with U.S. practice and which contain subject matter that is described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. Favorable consideration is requested.

The Examiner rejected claims 1, 4, 7, 8 and 12 under 35 U.S.C. 102(b) as being anticipated by WO 98/50091, and also rejected claims 2 and 9-11 under 35 U.S.C. 103(a) as being unpatentable over WO 98/50091 in view of "Hemodialysis Machines and Monitors" by Polaschegg et al. ("Polaschegg"). The Examiner further rejected claim 3 as being unpatentable over WO 98/50091 in view of Pedrini et al. ("Pedrini"), and claim 13 as being unpatentable over WO 98/50091 in view of German Patent No. 4240681.

By this Amendment, Applicants have cancelled claims 1-13, rendering the rejections technically moot. However, with respect to new claims 14-25, Applicants provide the following comments.

The present invention is directed to a hemodialysis and/or hemofiltration apparatus having an extra-corporeal blood

circuit for receiving blood to be purified and a hemodialyser and/or hemofilter communicating with the blood circuit. The blood circuit has an upstream supply line and a downstream supply line connected upstream and downstream, respectively, of the hemodialyser and/or hemofilter for supplying a substitution fluid. A measuring device, which is monitored by a control device, is used to detect and record at least one operational and/or blood parameter. Such measuring devices preferably include pressure sensors as well as sensors for the detection of hematocrit value or blood density. In response to the detected parameter value, the infusion rate ($Q_S$pre) of the upstream supply line and the infusion rate ($Q_S$post) of the downstream supply line are controlled by the control device in order to control the operational and/or blood parameter being measured.

If a deviation between a desired value and an actual value is detected, the control unit causes at least one of the infusion rates of the substitution fluid to be changed. As a result, the ratio between the infusion rates may be changed until the desired values of the operational and/or blood parameters are obtained. Accordingly, the controlled variable is the operational and/or blood parameter, and the output of the control

device is a change of at least one of the infusion rates ($Q_s$pre, $Q_s$post).

WO 98/50091 is also directed to a method for controlling a blood purifying device but, instead of controlling the operational and/or blood parameter, the control unit of WO 98/50091 acts only to ensure that the blood flow rate, the ultrafiltrate rate and the rate at which substitution fluid is supplied, each of which is controlled by a respective pump, are monitored and kept at desired values. There is no measurement of nor correlation made between an operational and/or blood parameter value and modifications in the monitored rates. Therefore, in WO 98/50091, the controlled variable is the flow rate of blood or a substitution fluid or the ultrafiltrate rate and the controller output is a corresponding actuation of the appropriate pump in order to keep the flow rate at a desired constant value.

This does not teach or suggest the control system of the present invention in which the operational and/or blood parameter is the controlled variable and the controller output is a change in at least one of the infusion rates of the substitution fluid.

Nor does the other cited art provide the necessary teaching. Pedrini identifies advantages with simultaneous pre- and post- dilution, as opposed to pre-dilution or post-dilution performed individually, but does not teach or suggest modification of at least one of the pre- and post-supply line infusion rates in response to measurement of an operational and/or blood parameter in order to control such parameter.

Polaschegg teaches adjustment of an operational parameter, such as transmembrane pressure, for the purpose of controlling an ultrafiltration rate, and also teaches a feedback control of the ultrafiltration rate. However, this is not the same as modifying the infusion rates of pre- and post-substitution fluid supply lines to control the blood parameter. In other words, in the prior art, an operational parameter is used to change the ultrafiltration rate or the ultrafiltration rate is used in the feedback control. In the present invention, by contrast, the infusion rate is used to control the blood or operational parameter. This is distinguishable over the prior art.

For at least the foregoing reasons, claims 14 and 20 are patentable over the prior art; favorable consideration is requested. Claims 15-19 and 21-25 are also in condition for

allowance as claims properly dependent on an allowable base claim and also for the subject matter contained therein.

Attached hereto is a marked-up version of the changes made to the application by the current amendment. The attached pages are captioned "Version with Markings to Show Changes Made".

With this amendment and the foregoing remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any questions or comments, the Examiner is cordially invited to telephone the undersigned attorney so that the present application can receive an early Notice of Allowance.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

On page 8, the third paragraph has been amended as follows:

-In a further embodiment means for controlling the at least one of the infusion rates ($Q_s$pre, $Q_s$post) are valves 16, 17 in the supply lines.--

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Anlage 2: WPindex-Abstract of DE 42 40 681

The apparatus has a dialyser divided by a semi-permeable membrane into a dialysis liquid chamber and a blood chamber. A dialysis liquid path passes through the dialysis liquid chamber and has a dialysis liq. supply at one end and a drain connection at the other end. An extra-corporal blood path passes through the blood chamber; whilst a blood pump is provided upstream of the blood chamber. A flushing liq. container is connected to the blood path, and an ultrafiltration device withdraws liq. from the blood through the membrane. The container is connected to the blood path by a connection line upstream of the blood pump, and an occludable actuator is provided in the connection line. A control unit, for operating the actuator, periodically switches the apptaratus so that in a first phase, the clamping action of the actuator is relieved to allow delivery of a certain flushing liq. quantity through the blood path by the action of the pump. In a second phase, the ultrafiltration unit is operated so that, in addn. to the blood serum quantity to be withdrawn from the patient, the supplied flushing liq. quantity is withdrawn from the patient.

ADVANTAGE - The appts. allows initial filling and flushing of the extra-corporal blood circuit with physiological liq. and allows automatic free flushing of this circuit with simultaneous liq. balance.